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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OLSEN, KAJ K	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,894	REEL ET AL.	
	Examiner	Art Unit	
	Kaj K Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Appeal

1. In response to the applicant's Appeal Brief, the examiner is reopening prosecution in order to introduce additional rejections drawn to art recently discovered. This will ensure that any future appeal will be drawn to a more comprehensive rejection of the claims. In view of this reopening of prosecution, this response is a *non-final* office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 5, 8, 9, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Papp et al (USP 5,422,272). Papp is being cited and relied on for the first time with this office action.

4. Papp discloses an analyte manipulation device and sample holder that comprises at least two coextensive electrically-conductive members (1, 2) disposed in fixed spaced relationship. See col. 3, lines 31-41. Papp further discloses a holder that is adapted for relative movement between a first position and a second position (compare fig. 4a and 4b) and further discloses an AC power source adapted for electrical communication with the electrically conductive members. See fig. 6 and col. 5, lines 39-60. Because Papp discloses the AC power source and the spaced apart electrodes, Papp would inherently be able to establish an electrical field gradient

within the holder. With respect to the device being for the manipulation of polarizable analyte, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, see col. 3, line 64 through col. 4, line 11.

5. With respect to the presence of resin material, see col. 3, lines 60-64. A "hardenable adhesive" would appear to read on "resin" giving the claim language its broadest reasonable interpretation.

6. With respect to claims 8 and 9, the conductive members of Papp have corners, edges, and points.

7. With respect to being configured as a handle, see col. 5, line 61.

8. With respect to a DC power source, see col. 4, line 60 through col. 5, line 60.

9. Claims 1, 4, 8, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (USP 5,304,486). Chang is being cited and relied on for the first time with this office action.

10. Chang discloses an analyte-manipulation device that comprises two coextensive elongated electrically conductive members 25 disposed in a fixed space relation. Fig. 5a, 7b, 8b, 10a and 13c all read on the claimed elongate members. Said members are disposed in a manner that allows for movement between first and second positions both inside and outside of a holder 13 (compare fig. 5a with 5b). Chang further discloses the presence of an AC power source for electrical communication with the conductive members. See col. 7, lines 59-66. Because Chang discloses the AC power source and the spaced apart electrodes, Chang would inherently be able to establish an electrical field gradient within the holder. With respect to the device being for the movement of polarizable analyte, that is only the intended use of the apparatus and the intended

use need not be given further due consideration in determining patentability. However, because Chang possesses the spaced apart conductive members and the AC power source, Chang would inherently be capable of trapping polarizable analyte.

11. With respect to claims 8 and 9, the conductive members of Chang have corners, edges, points, bumps, protrusions, etc. See any of the above mentioned figures.

12. With respect to being configured as a handle, see col. 13, lines 10-12.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-4, 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (USP 4,911,806) in view of Dahms (USP 4,124,470).

16. With respect to claim 1, Hofmann discloses an analyte manipulation device for moving polarizable analyte of interest that comprises two coextensive, elongated, electrically-conductive members (14, 16) disposed in a fixed, spaced relation within a sample holder 18 (fig. 1, and col. 4, lines 64-66). Hofmann also discloses an AC power source 26 in electrical communication with the members (col. 5, lines 3-22). However, it would appear the function of the AC power source is for the establishing of an appropriate field gradient (see col. 2-4). Hofmann does not explicitly disclose that the sample holder be adapted for relative movement from a first position to the second position as set forth by the claims. However, configuring a analyte manipulation device such that it could be utilized for a plurality of different containers (i.e. that it can pulled in and out of a particular analyte container) is notoriously well known in the art. In particular, Dahms discloses in an alternate separation device that structure for the manipulation of a particular sample may be configured such that the said structure is useable on a plurality of different sample containing vessels thereby facilitating automated analyzing (fig. 2-4 and abstract). Said structure must be adapted so that it can be moved from first and second positions (i.e. it must be raised and lowered into and out of the vessel currently being analyzed) via motors (col. 9, lines 17-20). Alternatively, the turntable of Dahm (indicated by the arrows of fig. 3 and 6) moves the analyte holders through different positions such that the different analyte holders can be aligned with the said structure. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the structure of Dahms for the device of Hofmann in order to allow a particular analyte structure to be useable for a plurality of different sample holders and to automate the analysis of the analyte.

17. With respect to claim 2, see Dahms (col. 9, lines 17-20).

18. With respect to claim 3, the turntable of Dahms moves the analyte holder toward and away from the manipulating structure (which in Hofmann are electrically conducting members).

19. With respect to claim 4 (those limitations not addressed above for claim 1), the moveable support of Dahm (col. 4, lines 17-20) supports the said analyzing structure (which in Hofmann are electrically conducting members). With respect to trapping a portion of a polarizable analyte in a concentration zone, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, that does appear to be the function of the device of Hofmann (see col. 2-4).

20. With respect to claims 8 and 9, the electrically conducting members of Hofmann inherently possesses edges or corners.

21. With respect to claim 11, an innumerable number of features of either Hofmann or Dahms could reasonably be utilized to function as a handle for holding the device.

22. With respect to claim 12, see figure 4 of Dahms.

23. Claims 1, 4, 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of either Papp or Chang.

24. Hofmann set forth all the limitations of the claims (see rejection above), but did not explicitly disclose making the device adaptable for relative movement. However, the newly cited Papp and Chang disclose devices for manipulating analyte in containers and teach making those devices movable in and out of a container. See the rejections above with Papp or Chang. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the movable teaching of either Papp or Chang for the device of Hofmann in order to allow a particular analyte structure to be useable for a plurality of different sample holders,

thereby increasing device flexibility. In addition, making the device movable would permit the ability to clean, sterilize and/or repair the device thereby extending the operable lifetime of the device.

25. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Papp or Chang in view of Dahms.

26. Papp and Chang set forth all the limitations of the claims, but did not explicitly recite the use of a control unit or holder-handling apparatus. However, it has been well established that merely automating previous manual operations requires only routine skill in the art. See In re Venner, 120 USPQ 192. This is particularly demonstrated by the previously discussed Dahms, which set forth such an automated device that allows for a particular analytical device to be inserted and removed from a given container (see rejection above). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dahms for the devices of either Papp or Chang in order to automate the manipulation device.

27. Claims 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann and Dahms as applied to claim 4 above, and further in view of Goldstein (USP 4,643,814).

28. Claims 6, 7, and 10 (and claim 5 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Papp in view of Goldstein.

29. Claims 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Change in view of Goldstein.

30. With respect to the claims, Papp, Chang or Hofmann and Dahms disclosed all the limitations of the claims, but did not explicitly recite the presence of either resin material or non-

conductive filament within the members. Goldstein teaches in an alternate separation device teaches that materials can be placed between electrically conductive members to facilitate the holding of the desired analyte material (col. 4, line 53 through col. 5, line 38). Among the materials contemplated include epoxy resin (col. 12, lines 5-10) and porous non-conductive filaments (e.g. see col. 4, lines 53-66). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Goldstein for the apparatus of any of Papp, Chang or Hofmann and Dahms in order to hold the materials that are being sorted, electroporated or fused.

31. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Papp or Chang in view of WO 00/49173 (hereafter "WO '173"). WO '173 is being cited and relied on for the first time with this office action.

32. The references set forth all the limitations of the claim, but did not explicitly recite the presence of two or more pairs of conductive members per support. However, it has been well established that merely scaling up a particular analytical device requires only routine skill in the art. In particular, WO '173 demonstrates this in an alternate analyte manipulation device where a plurality of analyte manipulating electrodes 57 are mounting on a given support so that a plurality of different holders can be simultaneously analyzed. See fig. 13 and 14 in particular. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '173 for the device of Papp or Chang in order to scale up a given manipulation device thereby increasing analyte manipulation throughput.

33. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of Dahm as applied to claim 4 above, and further in view of WO 97/41219 (hereafter "WO '219").

34. The references set forth all the limitations of the claim, but did not explicitly recite the addition of a DC power source for the electrically conducting members. WO '219 teaches that the use of DC voltages allows one to capture DNA from an analyte solution thereby allowing said DNA to be removed from the solution and later replicated or amplified (p. 1, lines 15-24). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '219 for the device of Hofmann and Dahm in order to capture the sorted DNA allowing said DNA to be replicated or amplified.

35. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang.

36. Chang set forth all the limitations of the claim, but did not explicitly recite the use of a DC power source. However, Chang repeatedly disclosed that the use of DC was old in the art. See col. 2, lines 12-49. Hence, one possessing ordinary skill in the art would recognize that incorporating the use of a DC power source would increase the utility of the manipulation device for conventional DC cell fusion as well.

Response to Arguments

37. Applicant's arguments filed 7-30-2004 have been fully considered but they are not persuasive. Applicant urges that Hofmann teaches away from the modification set forth by the examiner. In particular, applicant relies on discussion col. 5, lines 1-3 and lines 57-59 to support their argument. The examiner does not see how these passages read away from making the

electrodes movable in an out of a container. In particular, col. 5, lines 1-3 discusses how the coil 20 must be surround the region between the electrodes. How does this teach away from making the electrodes of Hofmann movable? Why wouldn't one possessing ordinary skill in the art make the coil and the electrodes movable together? It is unclear what bearing this cited passage has on whether it would have been obvious to one of ordinary skill in the art at the time the invention was being made to make electrodes movable for insertion into different containers. It is unclear why the applicant believes Hofmann would have to be disassembled in order for the electrodes to be removed. Rather one would merely need to make the electrode and coil an integral movable unit.

38. The other cited passage (col. 5, lines 57-59 (actually just lines 58 and 59)) discusses how baffles or other mechanisms are utilized to extract the samples. From this applicant construes that it would not have been obvious to utilize Hofmann to pick up and transfer a sample. It would appear here that the applicant has misconstrued the rejection in question because the examiner never suggested that the electrodes should be movable so that the device can be utilized to pick up and transfer a sample, and it is unclear how the rejection could have been interpreted in that manner. Rather the examiner suggested that making the electrodes movable would allow the electrodes to be utilized in a number of different containers (see the end of paragraph 5 of the final rejection). The reasoning for making the electrodes movable was so that they could be placed in a multitude of different containers. The examiner further urges that making the electrodes movable would also allow for there being cleaned, sterilized and/or repaired. It is unnecessary for the obviousness of the combination of the two references to be the same purpose as that of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
October 13, 2004

KAJ K. OLSEN
PRIMARY EXAMINER